

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Reissue Patent Application of: Bohn

Appln. Nos.: 09/077,194 and 10/606,229

Filing Date: December 4, 1998 and

June 26, 2003

Title: USE OF 1-HYDROXY-2-PYRIDONES FOR THE TREATMENT OF SEBORRHEIC

DERMATTTIS

DECLARATION OF R. TODD PLOTT, M.D. UNDER 37 C.F.R. § 1.132

I, R. Todd Plott, M.D., being of legal age, declare as follows.

- 1. I am Vice President for Clinical Research and Regulatory Affairs of Medicis Pharmaceutical Corporation ("Medicis"). I am also a board certified dermatologist.
- 2. I received my undergraduate degree in Biology/Chemistry and History from Bethany Nazarene College and my M.D. from University of Texas Medical Branch in Galveston, Texas. My internship and residency in dermatology was at the University of Arkansas of Medical Sciences. My fellowship in dermatology was at the National Institutes of Health, National Cancer Institute.
- 3. After my fellowship, I was employed by Hoechst Roussel Pharmaceuticals and then Rhone-Poulenc Rorer Company (Dermik Laboratories, Inc.) as Director of Clinical Research. I then became Director, Worldwide Clinical Development for Galderma Laboratories, Inc. Then I was Director, Clinical Research in Dermatology and Anti-Infectives/Dermatology for Schering-Plough Research Institute. My employment at Medicis began in 2001. As can be seen, I have had significant experience in product development and clinical research in the field of dermatological products.
- 4. As Vice President of Medicis, my responsibilities include oversight of the development of new dermatological drug products, and of the preparation of applications for regulatory approval by the U.S. Food & Drug Administration.

Brochure

- 5. I am familiar with the brochure prepared by Medicis, which is attached hereto as Exhibit A.
 - This brochure was prepared in part to educate physicians (especially those who are not dermatologists) about seborrheic dermatitis.
 - 7. The brochure points out that seborrheic dermatitis is sometimes confused with dandruff. While non-dermatologist physicians sometimes make this mistake, dermatologists know that seborrheic dermatitis is an inflammatory disorder associated with the hyperproliferation of keratinocytes, while dandruff is a "noninflammatory" scaling of the scalp. While both disorders can include flaking skin among their symptoms, they are known by dermatologists to be different disorders.
 - 8. This brochure points out that non-dermatologists are sometimes unaware of this distinction. (See p. 2, where the brochure mentions "mistaken.")
 - 9. Medicis no longer uses this brochure because, among other reasons, parts of it are not sufficiently clear and could be taken to confuse the distinction between these two disorders.
 - 10. This brochure also mistakes a common secondary infection associated with seborrheic dermatitis for a causative factor. "Seborrheic dermatitis of the scalp is a long-term condition that is thought to be caused by the overgrowth of a common fungus that naturally occupies the skin." While there may be secondary fungal infections, seborrheic dermatitis is not now thought to be caused by overgrowth of a fungus. I make this statement based upon my dermatology experience and work in this area.

All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any registration resulting therefrom.

Date: 1/17/04

R. Todd Plott, M.D.